January 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Re: Docket No. 02P-0462

Via Electronic Submission:
http://www.fda.gov/dockets/comments
e-mail: fdadockets@oc.fda.gov

1. Richardson Labs, Inc. ("Richardson") hereby submits its objections to the Petition filed by Carbolite® Foods, Inc. ("Carbolite") for the Use of an Implied Nutrient Content Claim in the Brand Name "Carbolite®" ("Petition"). Richardson markets a number of products under its Carb Solutions™ brand, including bars that compete with the bars referenced by Carbolite in its Petition. Previously, the FDA has taken the position that claims made on Carb Solutions products identifying the products for low carb diets are misbranded because the label contained nutrient content claims not authorized by regulation or the Act. *See FDA Warning Letter ONPLDS 10-01, April 26, 2001 to Richardson Labs.* While FDA has more recently advised that it "recognize[s] that there may be ways for a product to bear a low carbohydrate lifestyle claim or a claim of usefulness in a carbohydrate diet without the claim being considered a nutrient content claim," FDA has continued to affirm that "most uses of the term 'low carbohydrate' on a food label are in a context that characterizes the level of a nutrient and therefore, are unauthorized nutrient content claims." *See July 18, 2002 letter from John B. Foret, Director, Division of Compliance and Enforcement, CFSAN to William K. DeBraal, Florida Department of Agriculture and Consumer Services.* FDA's enforcement position has consistently held that low or lite carb claims relating specifically to a product are disallowed as unauthorized nutrient content claims. "Carbolite," as used on Petitioner's products, is clearly used as a nutrient content claim of the product being "light" or "lite" in carbohydrates, in violation of the uses authorized by 21 C.F.R. § 101.56.

2. A review of the United States Patent and Trademark Office records establishes that the Carbolite name was first used by Petitioner in commerce in January 1997. *See USPTO Official Gazette, September 3, 2002, TM 476.* Thus, Petitioner knowingly adopted a brand name that does not meet the criteria for the exemption of 21 C.F.R. § 101.13(q):

> "Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product **that was the brand name in use on**

> **such food before October 25, 1989,** may continue to be used as part of that brand name for such product, provided that they are not false or misleading under Section 403 (a) of the…Act…" (emphasis added).

At the time that Petitioner chose to use Carbolite, FDA's nutrient content claim rules were well established, including FDA's regulation that exempted only grandfathered trademarks in use before October 25, 1989. Favorable action on Petitioner's request puts companies such as Richardson that did not select an implied nutrient content claim as a brand name based on this regulation, at a clear competitive disadvantage.

3. FDA's regulations require that Total Carbohydrates include declarations for dietary fiber, sugars and as applicable, sugar alcohols. In warning letters to food companies, FDA has interpreted the Total Carbohydrate listing to require inclusion of e.g., sugar alcohols, fibers and other ingredients such as glycerin. While Richardson and other companies have provided additional information on their label differentiating between those e.g., net carbohydrates that impact blood sugar levels and should be counted toward daily carbohydrate intake from other "non-impact" carbohydrates that have a negligible impact on blood sugar levels and may be discounted by low carb dieters, the FDA's position is that ingredients such as sugar alcohols, while qualifying for a "no sugar" claim, must be counted as carbohydrates.

4. There are important underlying food labeling issues that are presented in the Carbolite Petition regarding the need for useful communication to consumers regarding the differences among the compounds FDA currently defines as carbohydrates. Some of these issues have been raised by Richardson previously to FDA as issues that should be reviewed by the Agency and the public in rulemaking. For example, the Nutrition Evaluation Division of the Health Protection Branch of Health Canada allows "low carbohydrate" claims for foods that contain less than or equal to 10% available carbohydrates and less than or equal to 2 g available carbohydrates per serving. *See 6.2.4.5 Summary Table of Carbohydrate Claims*. Excluded from available carbohydrates are substances that, when tested according to accepted methodology, do not result in a rapid changes in blood glucose or insulin. By granting Carbolite's Petition and allowing it to expressly refer to its products as "lite" in carbohydrates, how would FDA be quantifying a product that is "lite" in carbohydrates? The requirements for a claim using the term light or lite to describe a food have specific stated criteria, such as requirements that if a food derives 50 percent of more of its calories from fat, the fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference food, or if the food derives less than 50 percent of its calories from fat, the number of calories is reduced by at least one-third per reference amount. *See e.g., 21 C.F.R. §101.56 (b).*

5. The issues raised by the Petition are complicated and should be addressed by FDA in a broader rulemaking. Granting the Petition will allow Petitioner and Petitioner alone to make light carbohydrate claims for its products while Petitioner's competitors are prohibited from making such claims. As cited previously by Richardson to FDA in a December 13, 2001 letter on the above-referenced Warning Letter, case law suggests that FDA has an obligation to update its regulations consistent with new science and consumer interest. Clearly there is strong consumer interest in "low carbohydrate" diets and new science on the value of these diets. FDA's regulations define the diverse category of carbohydrates "by subtraction" and there are ingredients that by "default" fall into this category even though their chemical structure differs from the class of compounds generally recognized as carbohydrates, and their impact on blood glucose levels differs significantly from e.g., traditional sugars. Useful and updated accurate information should be provided to consumers in nutrition labeling.

6. For the reasons stated above, granting the Petition would give Carbolite an exclusive "license" to use an unauthorized nutrient content claim, in violation of both FDA's clear prohibition against brand name nutrient content claims in 21 C.F.R. § 101.13, and also its unequivocal enforcement position against low/light carbohydrate claims applied directly to products, taken in numerous warning letters to food companies. The underlying and important issues raised by Carbolite should instead be addressed in rulemaking that recognizes the importance for low/light carbohydrate product claims but defines the claim, consistent with FDA's existing nutrient content claims procedures.

Sincerely,

Deborah Shur Trinker, Esq.
Senior Vice President, Regulatory Affairs